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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,097	06/14/2001	Anton Wellstein	102728-P01-004	3830
28120 7590 01/31/2008 ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER KOLKER, DANIEL E	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 01/31/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/880,097

Applicant(s)

WELLSTEIN, ANTON

Examiner

Daniel Kolker

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 95,96,99-101 and 103-123 is/are pending in the application.
- 4a) Of the above claim(s) 106-118 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 95-96,99-101,104,119-120,122 is/are allowed.
- 6) ☒ Claim(s) 103,105,121 and 123 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

#### **DETAILED ACTION**

1. Claims 95 – 96, 99 – 101, and 103 – 123 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 1 October 2007 and 2 November 2007 have been entered.

#### ***Election/Restrictions***

3. Claims 106 – 118 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2 February 2004.
4. Claims 95 – 96, 99 – 101, 103 – 105, and 119 – 123 are under examination.

#### ***Withdrawn Rejections and Objections***

5. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection under 35 USC 102(b) over Morris is withdrawn in light of the amendments. Independent claim 95 now requires that the protein have no additional elements from ALK other than the PTN-binding region; this is not taught by Morris.

B. The rejection under 35 USC 102(b) over Caughey is withdrawn in light of the amendments. Independent claim 95 now requires that the protein have no additional elements from ALK other than the PTN-binding region; this is not taught by Caughey.

C. The rejection under 35 USC 101 is withdrawn in light of the amendments. Independent claim 95 now is drawn to a recombinant protein that excludes ALK protein outside the PTN-binding region. The invention requires the hand of man and therefore the rejection is withdrawn.

D. The rejection of claim 119 under 35 USC 112, second paragraph is withdrawn in light of the amendments which provide proper antecedent basis.

E. The rejections under 35 USC 102 and 103 as anticipated by or obvious over Pulford are withdrawn in light of the amendments. Independent claim 95 now requires that the protein have no additional elements from ALK other than the PTN-binding region; this is not taught by Pulford.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 103 and 121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are indefinite because they recite the limitation "in a therapeutically effective amount." It is unclear what the amount of the polypeptide is to be therapeutic for. The claims do not have a preamble that states any particular intended use of the claimed composition, and the specification does not specifically identify the disease to be treated by the composition. In the absence of specifically identifying a disease or physiological state to be altered by the composition, it is unclear what amount would be "therapeutically effective". See MPEP § 2173.05(c)(III).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 105 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 105 and 123 each require the presence of a substance that blocks the binding of PTN to ALK. The specification fails to describe what the structure of this substance is. While the specification generally describes screening methods to identify such substances, it does not describe the substances so identified. Of course what is identified in a screening assay depends upon the structure of the chemicals screened. The instant disclosure of a screening assay does not adequately support the scope of the claimed genus, which encompasses methods of administering a substantial variety of compounds of unlimited structure. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

Here, applicant has not described a reasonable number of members of the genus of compounds that are required to be included in the compositions, but rather has presented the public with an idea of how to perform an assay that might identify some agents that could be used in the methods. Of course, depending on what agents are used in the screening assay, it may well identify none.

The instant claims are often referred to as “reach-through” claims, where an applicant attempts to obtain patent protection on an invention not yet discovered. The Court of Appeals for the Federal Circuit addressed claims of this sort in great detail in *University of Rochester v. G.D. Searle and Co.* (69 USPQ 2<sup>nd</sup> 1886, CAFC 2004). In *Rochester*, the Federal Circuit upheld the district court’s ruling that patent claims which recited administration of compounds not disclosed, but rather to be identified in a screening assay, were invalid on their face. Here, the situation is analogous to that in *Rochester*. Since the specification does not disclose to the

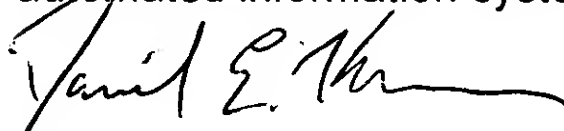
public the structures to be included in the claimed compositions, it does not meet the written description requirement of 35 USC § 112, first paragraph.

**Conclusion**

8. Claims 95 – 96, 99 – 101, 104, 119 – 120, and 122 are allowed.
9. Claims 103, 105, 121, and 123 are rejected.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
*Patent Examiner*

Daniel E. Kolker, Ph.D.

January 23, 2008